



## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

**[Docket No. DEA-819]**

### **Specific Listing for 4F-MDMB-BINACA, a Currently Controlled Schedule I**

#### **Substance**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration is establishing a specific listing and Administration Controlled Substances Code Number (drug code) for 4F-MDMB-BINACA (also known as 4F-MDMB-BUTINACA or methyl 2-(1-(4-fluorobutyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate) in schedule I of the Controlled Substances Act (CSA). Although 4F-MDMB-BINACA is not specifically listed in schedule I of the CSA with its own unique drug code, it has been controlled in the United States since April 2017 as a positional isomer of 5F-AMB, a schedule I hallucinogen. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include 4F-MDMB-BINACA.

**DATES:** Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

#### **SUPPLEMENTARY INFORMATION:**

#### **4F-MDMB-BINACA Control**

4F-MDMB-BINACA (also known as 4F-MDMB-BUTINACA or methyl 2-(1-(4-fluorobutyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate) is a chemical substance which is structurally related to 5F-AMB (also known as methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate). 5F-AMB is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(74). The introductory text to subparagraph (d) provides: (1) A listed substance includes “any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible,” and (2) the term “isomer” includes the optical, position[al], and geometric isomers.

When compared to the chemical structure of 5F-AMB, 4F-MDMB-BINACA meets the statutory definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term “positional isomer” in 21 CFR 1308.11(d). Both 5F-AMB and 4F-MDMB-BINACA possess the same molecular formula and core structure, and have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety between functional groups. Accordingly, under 21 CFR 1308.11(d), 4F-MDMB-BINACA, as a positional isomer of 5F-AMB, has been and continues to be a schedule I controlled substance.<sup>1</sup>

### **The Drug Enforcement Administration’s Authority to Control 4F-MDMB-BINACA**

This rule is prompted by a letter dated May 7, 2020, in which the United States government was informed by the Secretary-General of the United Nations that 4F-MDMB-BINACA has been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention). This letter was prompted by a decision at the 63rd Session of the Commission on Narcotic Drugs (CND) in March 2020 to schedule

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<sup>1</sup> 5F-AMB (and its isomers) has been subject to schedule I controls since April 2017, first pursuant to a temporary scheduling order (April 10, 2017, 82 FR 17119) and the subsequent one-year extension of that order (April 8, 2019, 84 FR 13796), and then permanently pursuant to a final rule which continued the imposition of those controls (Jan. 24, 2020, 85 FR 4211).

4F-MDMB-BINACA under Schedule II of the 1971 Convention (CND Dec/63/8).

Preceding this decision, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the Federal Register with an opportunity to submit domestic information and opportunity to comment on this action, Sept. 10, 2019, 84 FR 47521 and Dec. 31, 2019, 84 FR 72370. In both instances, FDA noted that 4F-MDMB-BINACA was already controlled in schedule I of the Controlled Substances Act (CSA) as a positional isomer of 5F-AMB, and the December 2019 notice stated that no additional permanent controls for 4F-MDMB-BINACA under the CSA would be necessary to fulfill United States' obligations as a party to the 1971 Convention.

As discussed above in this final rule, 4F-MDMB-BINACA – by virtue of being a positional isomer of 5F-AMB – has been controlled in schedule I of the CSA temporarily since April 10, 2017 (82 FR 17119), and permanently since January 24, 2020 (85 FR 4211). Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to 4F-MDMB-BINACA. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

### **Effect of Action**

As discussed above, this rule does not affect the continuing status of 4F-MDMB-BINACA as a schedule I controlled substance in any way. This action, as an administrative matter, merely establishes a separate, specific listing for 4F-MDMB-BINACA in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for the substance. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of 4F-MDMB-BINACA, who had previously been granted individual quotas for such purposes under the drug code for 5F-AMB.

## Regulatory Analyses

### *Administrative Procedure Act*

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. 4F-MDMB-BINACA is currently controlled in schedule I as a positional isomer of 5F-AMB, and 4F-MDMB-BINACA has no currently accepted medical use in treatment to qualify for placement in a schedule other than schedule I (*see* 21 U.S.C. 812(b)(2)-(5)).

Pursuant to 5 U.S.C. 553(b)(3)(B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures. The addition of a separate listing 4F-MDMB-BINACA and its DEA controlled substances code number in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of this drug as a schedule I controlled substance, but instead is “a minor or merely technical amendment in which the public is not particularly interested.” *National Nutritional Foods Ass’n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79-752, at 200 (1945)). *See also Utility Solid Waste Activities Group v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001) (the “unnecessary” prong “is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public”) (int. quotations and citation omitted). This rule is a “technical amendment” to 21 CFR 1308.11(d) as it is “insignificant in nature and impact, and inconsequential to the industry and public.” Therefore, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary.

In addition, because 4F-MDMB-BINACA is already subject to domestic control under schedule I as a positional isomer of 5F-AMB and no additional requirements are

being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3). DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of 4F-MDMB-BINACA. 4F-MDMB-BINACA is currently controlled as a schedule I controlled substance, and this level of control does not change with this rulemaking.

*Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. This rule is not a significant regulatory action under E.O. 12866. 4F-MDMB-BINACA already is a controlled substance in the United States under schedule I, as it is a positional isomer of a schedule I hallucinogen, 5F-AMB. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list 4F-MDMB-BINACA in schedule I and to assign the DEA controlled substances code number 7043 to the substance. A separate listing for 4F-MDMB-BINACA and its DEA controlled substances code number will not alter the status of 4F-MDMB-BINACA as a schedule I controlled substance.

Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

*Executive Order 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132, Federalism*

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the

relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175, Consultation and Coordination with Indian Tribal Governments*

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

*Paperwork Reduction Act of 1995*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

*Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for

inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

*Congressional Review Act*

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

**PART 1308 – SCHEDULES OF CONTROLLED SUBSTANCES**

1. The authority citation for part 1308 continues to read as follows:

**AUTHORITY:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. Amend § 1308.11 by adding paragraph (d)(87) to read as follows:

**§ 1308.11 Schedule I.**

\* \* \* \* \*

(d) \* \* \*

(87) methyl 2-(1-(4-fluorobutyl)-1*H*-indazole-3-carboxamido)-3,3-

dimethylbutanoate (4F-MDMB-BINACA, 4F-MDMB-BUTINACA).....7043

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**D. Christopher Evans,**  
*Acting Administrator.*